NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES (NASCSA)

18th ANNUAL EDUCATION CONFERENCE
October 22 – 26, 2002
Myrtle Beach, SC

Note 1) Slides from most of the presentations, workshop reports and full text of resolutions are available on NASCSA's web site: www.nascsa.org

Note 2) Additional information for many of the presentations is available in the conference book.

WEDNESDAY, OCTOBER 23, 2001

Welcoming Remarks
Tim Benedict, Chair of Executive Committee, and Ohio State Board of Pharmacy

Introduction of Executive Committee.
Request for attendees to identify potential speakers for future conferences.

Opening Remarks
Bill Ward, President of NASCSA, and, Chief of Enforcement Operations, Department of Consumer Protection, State of Connecticut

President Ward thanked the fifteen sponsors for their generous support of NASCSA. He then presented NASCSA's Mission Statement and described NASCSA's organization and activities. NASCSA now has 43 member states with FL and TN as new members. He also introduced other officers:

Vice President	Dana Droz
Secretary/Treasurer	James Giglio
Members of Executive Committee	Karen Tannert, Wilbur Harling, David Dryden, and Keith MacDonald.

He discussed officers' duties and NASCSA's accomplishments for 2001-2002:

- Obtained independent non-profit status.
- Suggested a change in policy for resolutions.
- Developed proposed by-law changes.
- Participated in meetings with national organizations.
- Attended DEA meeting in St. Louis.
- Participated in RADARS Workgroup with Purdue Pharma.
- Reviewed information for NASCSA's Website and email distribution.
- Maintained NASCSA's Website, www.nascsa.org

Future conferences will be held October 21-25, 2003 in Biloxi, MS and October 19-23, 2004 in San Diego, CA.

President Ward thanked NASCSA's Executive Director, Kathy Keough, for all her work in conference preparation and operation. He thanked John Eadie for recording the conference proceedings for this and previous years' conferences.

Note: The list of sponsors, the Mission Statement, and other information are available by downloading William Ward's Introduction and Overview of NASCSA slides on the website: www.nascsa.org

Who Survives the Media and Why: Guerilla Media Tactics 101

Eric Dezenhall, Nichols-Dezenhall Communications Management Group, Ltd.

Mr. Dezenhall described his work as being in the damage control business.
He authored the book, N*ail'em: Confronting High-Profile Attacks on Celebrities and Businesses.* The book describes how the media often tries to "nail" people as a method of operation, justified or not.

There are common myths that Americans believe and the media utilizes to "nail" people. A primary myth is that "corporations are in absolute control of what goes on in the company - the fallacy of evil men." The reality is that corporations are not in total control, and leaders of corporations do not try to think of ways to harm people. A second myth is that "a crisis is an opportunity to get our message out." It isn't so. Good management can mitigate the crisis into less damage, but the damage and pain are still great. Martha Stewart's crisis is an example.

A third myth is that "a crisis is a public relations problem." Not so. A crisis is a crisis and must be dealt with on multiple fronts or business/activity will suffer. Another myth is that "apologies always work." This is not true. They may help in some circumstances but much more is required to stop attacks.

The Culture of Attack:
Attacking other people has become part of the American and media dialogue. Attacks are now commonplace in our litigious climate with court cases over many issues that previously were settled outside of court. The "sympathetic media" thinks that the only problem is greed, i.e. corporate money making. They forget that another problem is the drive for fame, the drive that motivates media to over react. The media also misses that sophisticated competition can lead competitor companies to attack other corporations to advance their own products. In our culture today, there is a "Zero-time" information relay so that attacks can get out and be spread like wildfires. As long as an attack sounds plausible, the public may believe it, even if isn't true.

Part of the reason for attacks is the explosion of TV news magazines, 24-hour cable news networks, and internet media. They have to fill the time and explain their role by attacking celebrities and high profile corporations.

Origins of Conflict:
People generally resolve specific disagreements by addressing each other and working out their differences. However, ideological / worldview issues are much harder to resolve / overcome. It is easier to blame others than work out differences.

Two Types of Peace:
When people or organizations share values, they can work out differences around the shared values. An alternative route to peace is for one party to use greater power, i.e., threaten someone with lawsuit, or other harm so they will back off and stop an attack.

Packaging Attacks:
Usually, the media "wins" simply by making allegations; they don't have to prove the allegations. To make an attack work, the media need:

- Villain – person/corporation who has harmed someone.
- Victim – person harmed.
- Vindicator – "we're helping people."
- Vehicle – television, radio, newspaper, magazine, or the Internet.
- Value – people must find that the villain did something that violates their values.
- Void – the media has to have a void in news to fill or won't attack.

Cyber Attacks:
The term "Flaming" means false attacks over the Internet. An example is Tommy Hilfiger, who was attacked for racist statements that he never made. But his clothing sales never recovered. Another example was rumors that diapers cause asthma because they have fluff in them. It turned out that a doctor with a financial stake in "all natural" diapers started the rumors. Another example was that "kidney

thieves" were operating in New Orleans. The rumor that someone stole a person's kidneys was totally false but tourism dropped.

Exposing Internet Attacks:
If false attacks are made, people must respond and refute them -- silence is considered to be acknowledgement.

Dezenhall authored another book, *Money Wanders.:* fiction about how spin disinformation works. It describes "Electric snipers," people who attack in media all the time, and "Evanjournalists" who apply religious zeal to attacking others.

Factors in Survival:
When corporations are attacked, they must determine the "Allegation resonance," i.e. is the allegation true, and the Facts, e.g. did anyone die and does anyone care? They must also evaluate the "Pre-existing cultural values," for example, the public perceives health care professionals are good, but questions the amount of money physicians make; pharmaceutical manufacturers are perceived to be making too much money.

Handling the crisis:
To respond to a crisis, CEO leadership must be strong, and a quick response is essential. The corporation or group must make a demonstrable response that does not have to be perfect, but must be strong and visible. Then, they must make a potent defense and be consistent in everything said and done -- leave no "chinks in the armor" for opponents.

Chance – problems happen:
Corporations and groups must determine the nature of a crisis. Is it a "character" crisis, i.e. "you are bad people" like Enron, Martha Stewart, Arthur Anderson, and Breast implants, or is it a "Sniper" crisis" like poison being put into Tylenol pills and the sniper in the Washington, DC area (where an outside force or person creates the crisis). The Pepsi crisis ended when video camera showed person in store putting syringe in Pepsi can, so the manufacturer clearly did not do it.

What businesses under attack must do:
They must attack the attackers by a number of strategies. They can "Highlight Hypocrisy," as when Liz Taylor spoke for AIDS research & animal rights, people pointed out that AIDS research requires use of animals. They can "Marginalize the Critics" by showing that there are other problems at work, e.g. "multiple chemical sensitivity" activists were essentially bogus. Another example was when Browning Ferris Industries waste haulers started work in NY and the mafia threatened BFI. The company's response worked when media publicized that the head of BFI was former head of FBI.

People must realize that niceness does not work when an attack is made; it is viewed as weakness. They also must realize, "you have no future with the attacker," and that "spin" is a myth, so don't rely on it unless people want to believe it. Instead people being attacked must look for their own greatest strength and the attackers' greatest weakness. Slander suits seldom work because, to win one, the attacked person or organization has to prove intent.

The objective must be to stop the attacker, not to make people feel good, like PR does. But attackers must be put at risk by tearing down their "mantle of virtue;" witch hunts stop when the general population is attacked, not just fringe people. People under attack must do research about the attackers and dissuade the attackers.

Q&A -- Does "No comment" work? Only occasionally; it is best to give a longer answer, like, "We are researching the issue, it is very complex and a response will take time."

What about the public view of pharmaceutical manufacturers? The public will never believe that companies making lots of money are good. The public already believes that pharmaceutical manufacturers make beneficial products, but will not see manufacturers as "good."

DEA Update
Patricia Good, Chief, Liaison & Policy Section,
Office of Diversion Control, US Drug Enforcement Administration.

Drug Trends:
The National Household Survey on Drug Abuse was published by SAMHSA with data for year 2000 in 2001. Highlights are that 14 million people (6.3% of US population) were current illicit drug users, and 3.8 million used prescription-type psychotherapeutics non-medically --mostly pain relievers, tranquilizers or stimulants. Also, there has been a very rapid rise in abuse of pain relievers with the sharpest rise in last few years of 1990s.

In 2000, the Drug Abuse Warning Network (DAWN) reported Emergency Department Mentions. Licit controlled Substances were 11 of the top 15 most frequently mentioned drugs. DAWN reports for the years 1995 to 2001 show that alprazolam mentions were rising, diazepam mentions were slowly decreasing, hydrocodone mentions were rising rapidly, doubling in the past 5 years, and oxycodone mentions increased 400% since 1996, and were very rapidly rising in 2000 and 2001.

DEA has also looked at the frequency of DAWN mentions against the volume of prescribing for several controlled substances. For oxycodone prescriptions, the DAWN mentions are increasing per 100,000 Rx. Clonazepam is the most abused of benzodiazepines, per 100,000 Rx, though decreasing slightly in 2000 and 2001. Other benzodiazepines are staying at the same levels as before, per 100,000 Rx.

Retail Sales 2001:
In total retail dollars, OxyContin had $1.5 billion in sales, making it #15 of all brand name Rx, an increase of 41% from year 2000. Hydrocodone / APAP had the highest generic controlled substances sales with $1.2 billion, a 20% increase from year 2000.

DEA statistics:
Registrants are about the same number as in prior years: 1 million retail level and 11,300 wholesale level. DEA has 400 field investigators, and they completed 3,097 investigations in 2001. The investigations were almost evenly divided among four groups, doctors, chemicals, scheduled investigations, and non-registrants. There were also a small number of pharmacy and other registrant investigations. Out of about 1 million registered physicians, 861 were investigated in 2001, a tiny portion. Out of 61,000 pharmacies, 175 pharmacies were investigated. In 2001 DEA took 502 surrenders of Registrations for cause, made 78 arrests, issued 63 admonition letters, and conducted 40 administrative hearings.

E-Commerce:
The Government Paperwork Elimination Act of 1998 requires that government paper work must be available electronically by October 2003.

E-sign:
Electronic signatures for global and international commerce have been operational since June 2000.

DEA is making two major electronic initiatives, both using PKI (Public Key Infrastructure) technology. The first is for Electronic Controlled Substances Prescriptions. This will affect 400-600 million Rx per year and 1 million practitioner registrants. Certificate Authorities will be authorized by DEA to issue digital signatures (not electronic signatures) and controls. Physicians will be required to access their private keys with smart cards or biometrics. The system is being tested by the Veterans Administration with computer simulations now, and real tests with VA physicians in November 2002.

DEA is also developing the Controlled Substance Ordering System (CSOS) for 300,000 registrants. It will be used in place of existing paperwork systems, albeit optional for the registrants. It will be able to be used for drugs in all controlled substances schedules and reporting to DEA will be within 48 hours. Tests

are underway with 12 firms in Healthcare Management Distribution Association (HDMA). States may need to modify their laws and regulations to make these new processes work.

Harold Rogers Rx Drug Monitoring Programs (PMPs) Grants:
DEA anticipates that by the end of October 2002, the Bureau of Justice Assistance will announce that four states will receive grants to start new PMPs and five states will receive grants to enhance existing programs.

National All Schedule Prescription Electronic Reporting Act NASPER:
A bill is being considered in Congress for a national database on C II, III and IV Rx. DEA did not introduce the bill, nor is DEA in support. The bill would set up national monitoring system in DHHS, providers could access their patients' Rx information, and law enforcement could access for investigations and enforcement.

Drug Addiction Treatment Act:
FDA has approved buprenorphine as a drug for addiction treatment for office based treatment. It will be available by Rx from specified physicians. DEA will issue special registration to the qualified physicians and will monitor process vis a vis diversion, and report to Congress. (Details of the program are reported in 2000 and 2001 NASCSA conference summaries and in this summary, see Nick Reuter's presentation on Saturday, October 26, 2002.)

Surplus drugs and Long Term Care Facilities (LTCFs) Regulations:
DEA received public comments regarding the proposed regulations and will allow pharmacies to register at LTCFs to use automated dispensing systems. Final rules for central fill locations are being developed.

Pharmacy Theft Prevention Program:
DEA is developing this program with the National Association of Chain Drug Stores (NACDS).

The next DEA conference of state agencies will be in May 2003 in Phoenix, AZ.

For information about this and other information, go to DEA's Diversion Control Program Website at:
www.DEAdiversion.usdoj.gov

Frank Sapienza
Chief, Chemical & Evaluation Section,
Office of Diversion Control, US Drug Enforcement Administration.

Drug Scheduling Update:
DEA has completed the following recent scheduling actions:

- Buprenorphine – all forms from CV to CIII 10-7-02.
- MDMA like drugs: 2CT-7, BZP and TFMPP, 9-20-02 -- Emergency (temporary) scheduling to CI.

A Federal Court of Appeals upheld DEA's denial of petition to remove marijuana form CI, 5-24-02.

International Scheduling:
WHO Expert Committee on Drug Dependence looked at the following in 2002:

- Buprenorphine in CIII of Psychotropic Convention – no action.
- Tramadol – not controlled now – no action.
- Dronabinol – moved CII- CIV (could open up potential for rescheduling marijuana).
- Diethylpropion – CIV – no change.
- Amineptine – not controlled now – to CII.

Petitions In Process:

- Hydrocodone CIII to CII.
- Methylnaltrexone – decontrol.

- Thiafentanyl – CII.
- Sibutramine (Meridia) – Decontrol from CIV – 1999 petition.
- Industrial Hemp.

Other Reviews are underway:

- Adrostenedione and related steroids.
- Carisoprodol: DEA review sent to DHHS in 1997 – concluded that data were anecdotal. It is still the most diverted non-controlled drug according to DEA field offices. It is rising to the level of diazepam in overdoses reported in DAWN. From 1997, the number of carisoprodol exhibits from investigations has quadrupled. While carisoprodol Rx are increasing, DAWN overdose mentions are going up even more rapidly. The drug is rarely abused alone, but usually with opiates. There is no systematic scientific studies of the drug's reinforcing effects, and the human, in vivo production of meprobamate as a metabolite. (charts with additional information is available in slides at NASCSA website.
- Oxycodone
- Ecstasy / other analogues.

Steroid Metabolic Precursors:
DEA is reviewing the "Mark Maguire" phenomenon. Marketed as food supplements, steroid metabolic precursors convert to controlled steroids when ingested. They are reported to produce much of the anabolic steroid cluster of effects. DEA is currently studying to see if they produce increased muscle mass. If so, these precursors may be designated as anabolic steroids.

OxyContin:
Abusers of OxyContin crush the pills into powder, mix it into a solution and inject it. Abusers report that they use the drug for euphoric effect. The DEA went to National Association of Medical Examiners to obtain information on OxyContin abuse. They asked for information on deaths for which there were positive oxycodone findings. The reporting is voluntary and confidential, and provides toxicology, autopsy and investigation reports to DEA. For 2000 – 2001, DEA has received 1,304 reports, including information from 32 states.

Of these reports, 134 were excluded for reasons such as the deceased had AIDS, or the persons died violent deaths. Another 221 were excluded for insufficient information.

A total of 148 deaths are associated with OxyContin because OxyContin pills were found in the stomach or the person had an Rx for the drug. Another 318 deaths were likely associated with OxyContin, due to high levels of oxycodone in the blood with no acetaminophen or salicylates. The remainder were undetermined.

Oxycodone deaths:
The mean age of the deceased was 40. The genders were 65% male and 35% female. Less than 20% of the deceased were found to also have cocaine, etc. For those whose deaths were attributable to oxycodone, the mean blood concentration was 0.411 mg/L, with a range of 0.001 to 16 mg/L.

OxyContin deaths:
The 466 deaths likely to have been associated with OxyContin had much higher blood concentrations of oxycodone; the mean was 1.16 mg/L and the range was 0.01 to 50 mg/L. Only a few OxyContin deaths were associated with injecting (10 deaths) crushing (2) or snorting (2). In many of the OxyContin deaths other substances were also identified, many of them being drugs normally involved in a pain treatment regimen, like alprazolam, 40%; other opiates like methadone, 40%; and antidepressants like Elavil, 30%; and over-the-counter drugs like benadryl, 14%. Only 15% of the deaths were also positive for cocaine.

New drugs of abuse:
State, federal and local law enforcement agencies are reporting new drugs of abuse, including piperazine derivatives, i.e. benzopiperadine (BZP) and trifluoromethyphenylpiperazine (TFMPP); and amphetamine

and tryptamine derivatives, 2CT-7; 5-Me-DIPT; and others. These drugs began showing up in DEA and state reports in 1997. They are often sold as Ecstasy (MDMA). Three deaths due to 2CT-7 have been reported in TN, OK and WA states. They are clandestinely produced or shipped in from overseas chemical suppliers. DEA has classified BZP, TFMPP, and 2CT-7 as Schedule I, effective 9/20/2002.

5-methyoxydiisopropyltrytatmine, 5-Me-DIPT, is an orally active tryptamine called "Foxy" or "Foxy Methoxy." It produces visual and audio hallucination (like LSD) and euphoria, body buzz and intense energy (like Ecstasy). It is structurally similar to DMT – a "Religious group" has sued Federal Government to block CI scheduling for DMT when it is used for "religious purposes." Salvia Divinorum – a Mexican product – is being sold on the Internet .

Business Section I – Committee Appointments, Announcements
Bill Ward, President, NASCSA

President's Award
Richard "Mick" Markuson, Executive Director, Idaho Board of Pharmacy, is awarded the NASCSA President's award in recognition of years of service to pharmacy, pharmacy education, his state, and NASCSA.

Committee appointments:
Auditing Committee
Jim Giglio, Chair
Charles Ray Nix

Resolutions Committee
David Dryden, Chair
Grant Carrow
Mark Healy

By-Laws Committee
Dana Droz, Chair
John Womble
Joanie Quirk

Nominations Committee
Tim Benedict, Chair
Don Williams
Mick Markuson

Pain and Addiction: New Regulatory Approaches to the Opioids
Nathaniel Katz, M.D., Director, Pain Trials Center, Brigham and Women's Hospital, and Assistant Professor of Anesthesia, Harvard Medical School, Boston, MA

Opioids have been used to treat pain for more than 4,000 years. An Egyptian physician described addiction to opioids in 300 BC. Over the long period since then, seldom has use of opioids been appropriately balanced between beneficial treatment and efforts to limit addiction.

Dr. Katz started a pain management center in Pittsfield, MA. One of his cases was a 32-year old man with foot crush injury. He was stable on Vicodin, 2 tabs QID. No toxicology screens were done because the patient kept providing rational sounding excuses. Later, he was admitted to a detoxification center for heavy heroin abuse. His employer discovered that he had stolen thousands of dollars. Then the health care staff realized why the patient had constantly worn long sleeve shirts, to hide his needle tracks.

Recent articles highlight the public concerns about opioid abuse. For example an article in the South Florida Sun-Sentinel on October 3, 2002 was entitled "Prescribed painkillers are killing patients." The article describes a physician who prescribed high doses of opiates for a patient who overdosed and died. The same paper, in May, had reported 400 deaths during past two years ... from prescription drug abuse, many ordered by doctors to control discomfort..."

Some studies of patients with non-malignant pain report that patients who have no substance abuse history or psychopathology show long-term benefit from opiate treatment without significant risk. Also, some studies of pain patients with substance abuse or psychopathology history show some reduced pain after they have gone through detoxification and have abstained from opioid use for a long period of time

However, only a few hundred patients have been studied in well designed prospective studies where patients were on long-term opioid therapy. Dr. Katz concludes that the effect of tolerance when patients are treated for chronic pain with opioids on a long-term basis has not been systematically studied or published in medical literature.

Pain in patients in Methadone Maintenance Treatment Programs (MMTP):
He has reviewed a survey of 250 patients in 3 MMTP centers. The survey found that 61.3% reported moderate to severe chronic pain, with average pain duration of 10 years. Their average time on MMTP was 8.5 years. Dr. Katz concludes that a subgroup of the highest risk patients can benefit from long-term opioid therapy for pain. However, other patients are better off not being treated with opioids. The critical thing in treating high-risk patients for pain is they must be in the in the right treatment setting with skilled medical supervision.

Risks of Opioid Therapy:
"Physical dependence" is common for patients on opioid therapy. It is a withdrawal syndrome related to cessation of medication, significant reduction in dosage or antagonist is administered. "Tolerance" is also common. It is the need for increasing doses of medication to maintain relief, or the therapeutic benefit is lost over time. "Pseudoaddiction" is experienced by some patients. It is behavior suggestive of addiction that is related to under-treatment of pain. "Addiction" (Psychological dependence) is also a risk. It is the compulsive use of a substance even when it causes harm; the patient loses control over drug use.

Acute pain "studies" have been extrapolated to chronic pain:
A primary example is a letter from Porter and Jick that was published in JAMA. This letter has been misused to say that there is no addiction with chronic use of opioids. The letter only said that use of opioids is effective for acute pain while patients are in-hospital and the patients showed no signs of addiction. But Porter and Jick did no follow-up the patients after discharge. There have been no prospective or controlled studies of treatment of chronic pain patients with opioids vis a vis addiction.

Dr. Katz has followed 20 chronic pain patients who had histories of substance abuse and were treated with opioids. His findings are that eleven had good outcomes; their history was of primary alcohol abuse, and they had good family support and had membership in AA or a similar group. Nine of the patients had bad outcomes; their history was of poly-substance abuse, and they had poor family support and no membership in support groups.

In a study of 122 patients, 53 (43%) had problems with positive urine screens and/or behavioral issues.

National data shows an increase in emergency department mentions of overdoses involving narcotic analgesics, and more people use analgesics non-medically than any other group of prescription drugs.

He concludes that even an astute clinician who relies on clinical assessments and patient self-reports does not actually know what is going on with many of the patients on chronic opioid therapy. He recommends to physicians treating patients with opioids that they get urine screens for illicit and other licit substances.

In addition to problems with addiction, opioids affect the endocrine system:

Studies show that opioids lower testosterone in animals, heroin addicts, methadone maintenance patients, and intrathecal opioid patients. A group of 25 male patients being treated for chronic pain with long-term opioid therapy had significantly lower testosterone levels than healthy controls.

Other problems reported with long-term opioid therapy include depression, low muscle mass, osteoporosis, and bone fracture. It is possible that these problems may be due to opioids' effects on the endocrine system, particularly low testosterone. Studies conducted in the 1800s showed feminization of male opium farmers in India.

Another of D. Katz's cases was a 48-year-old male who had been fully worked up for refractory headaches in UT and was being treated with Percocet. The patient moved to NH and sought care from Dr. Katz. His urine screens were clear. Dr. Katz prescribed Percocet until he was telephoned by another physician who was also treating the patient, unbeknownst to Dr. Katz. He learned that the "patient" was getting Percocet from 6 or 7 other physicians. When Dr. Katz confronted the patient, the patient never returned.

Prescription Monitoring Programs (PMP) can help physicians supervise patients on chronic opioid treatment. To do so, PMPs need to be crafted into patient monitoring and research tools to help the health care system identify patients with problems and patients who need improved treatment. To do this there is a need for legislative authorization and funding, as well as regulatory changes.

Dr. Katz has looked at Massachusetts' PMP data. In 2000 there were 1 million opioid Rx with a mean of 11.6 days' supply and a mean pill count of 49.9. The prescriptions were dispensed to about 540,000 individuals (9% of the population), with an average of 2 Rx per person. 194,000 Rx were issued with 90 or more pills. 220,000 (20%) of the Rx showed a maximum days' supply of 30 days.

Conclusions:
Opioids are essential for pain management. Opioids are associated with complications, including addiction, of which little is known. External patient monitoring is necessary for rational patient management. PMPs are a potential partner in addressing this challenge.

Workshop: National All Schedule Prescription Electronic Reporting Act (NASPER)
Patricia Good, Chief, Liaison & Policy Section,
Office of Diversion Control, US Drug Enforcement Administration

Congress has been reviewing OxyContin prescribing and abuse levels in hearings and through a GAO study (in conference book). DEA advised Congress the best way to address this is through expansion of state prescription monitoring programs (PMPs). As a result, Congress authorized $2 million for the Harold Rogers Prescription Monitoring program grants to fund new PMPs and to enhance existing ones.

A small group, the American Society of Interventional Pain Physicians (ASIPP) and a software vendor in the same locality in Kentucky are pushing for a new national system, NASPER. The software vendor believes it can implement NASPER with its software. Members of Congress are pushing for the bill and DEA has had to respond with comments several times.

The House has recessed so is not likely to consider the legislation this fall. The Senate may mark up the bill this week.

Grant Carrow, Ph.D., President, Alliance of States with Prescription Monitoring Programs, and Director, Drug Control Program, Massachusetts Dept. of Health

Senate S.3033 and House bill H.R.5503 are the NASPER bills. NASPER's objective is to set up a national program in the Department of Health and Human Services (DHHS) for physicians to access regarding patient treatment. This would create a huge database that will have to be managed, and the

Federal government has a poor history of operating such large systems. The Alliance of States with Prescription Monitoring Programs has developed a new PMP Model Act, which is a better way. It sets standards for data fields that states should collect. Federal moneys that would have funded NASPER (possibly as much as $15 million) would better used if provided to states to develop new PMPs.

States are concerned that, if NASPER is enacted, no new states will start PMPs and states with existing PMPs may drop their programs, due to state budget constraints.

Tim Benedict, Chair of NASCSA's Executive Committee, and Ohio State Board of Pharmacy

The NASPER legislation contains significant deficiencies. It will end up requiring nursing homes and correctional facilities to report every controlled substance administered to inpatients. It will allow nurses or any other person who is administering CS to access systems, but states and other agencies that should have access for research will be blocked from access.

The legislation will allow state PMPs to continue, but states must dump their data into the Federal program in the Federal format, forcing major changes in states' programs. It will also block states from charging prescribers or dispensers for the costs of their PMP, interrupting existing funding mechanisms in many states.

Reportedly, the Pharmaceutical Research and Manufacturers of America (PhRMA) is not going to take a position vis a vis NASPER. Some individual pharmaceutical manufacturers may choose to oppose NASPER.

THURSDAY, OCTOBER 24, 2002

Prescription Monitoring Programs: Balancing All the Issues
Grant Carrow, Ph.D., President, Alliance of States with Prescription Monitoring Programs, and Director, Drug Control Program, Massachusetts Dept. of Health

Update on Prescription Monitoring Programs (PMPs):
The goals of PMPs are: education and information for the public and health care professionals; public health initiatives to improve prescribing and protect health and safety; early intervention and prevention of prescription drug abuse; investigation and enforcement when violations occur; and protection of patient confidentiality.

The goals of Drug Control are symbiotic: A) to ensure pharmaceuticals are available for medical use and B) to prevent illicit sale, use and abuse.

PMPs are particularly good at addressing theft, burglary, robbery of drugs, illegal sales of drugs and prescriptions, doctor shopping, and tampering. Eighteen states have PMPs, including Tennessee and Virginia, that are just setting up PMPs after passing statutes in 2002. A satellite photograph of the US at night shows where states with PMPs are, i.e. the areas with the brightest lights are the states where PMPs operate -- eight of the ten largest metropolitan areas are in states with PMPs.

A cardigram (a map showing the size of states based upon population, rather than geographical area covered) shows that PMPs cover half the US population.
WA and VA have limited programs – WA's is for disciplinary purposes only and VA's is limited to one geographical area.

PMPs with serialized Rx are in the three states with the largest populations: CA, TX and NY. Half of the next twelve largest states also have PMPs. States with PMPs contain about 50% of US population and 46% of practitioners.

A major initiative of state PMPs is to send doctor-shopping reports to practitioners. While this is a relatively new development, it is expanding rapidly. Massachusetts has experienced a steady and rapid growth in CII Rx, with a two and a half time increase from 1993 through 2001. MA profiles the data and forwards information: 64% of cases to DIU, 20% to DCP, and 125 to BRM.

Twenty-eight states are members of the Alliance of States with Prescription Monitoring Programs.

A new Model Act for state PMPs was adopted at the Alliance's conference on October 22, 2002. This is a "Best Practices" act and is a consensus document supported by states with experience running PMPs and affiliate states with longstanding interest in PMPs. The Model Act establishes a legislative framework, and individual states may add provisions to meet their unique circumstances. The Act is based upon NASCSA 1996 model act, the Alliance's Consensus Statement on Data Elements of 1996, NASCSA resolution 2001-04, and National Alliance for Model State Drug Laws draft model act of 2001.

Key provisions of the Model Act include:

- Minimum standard for collection of information on all CII-CIV Rx.
- Key data elements that each state should collect.
- An option for serialized Rx forms.
- Protections for privacy and confidentiality of data.
- A list of persons and agencies to which data may be released.

The Model Act will be available from NASCSA's website at, www.nascsa.org/monitoring.htm.

Q&A: Will prescribers or dispensers in one state be able to obtain PMP information regarding their patients from other states? Response by Grant Carrow: Yes, current PMPs are able to and do share information across state lines. Further, the new Model Act makes eligible to receive PMP information any prescriber or dispenser who is authorized to prescribe or dispense CS.

What about states that don't currently have a PMP? What are the plans for them? Response by Grant Carrow: They can utilize the new Model Act and can receive assistance from states with PMPs through the Alliance. Hopefully, additional funding will be available through the Harold Rogers Prescription Monitoring Program federal grants.

Mary Ryan, Vice President, Regulatory Affairs, Merck-Medco Managed Care

Merck-Medco's (MM) client base is retail/home delivery of prescription drugs to 65 million people. MM managed $30 billion in Rx sales in 2001 through two "state-of-the-art," fully automated pharmacies. MM employs 2,500 pharmacists and they process 1.5 million Rx per week.

Merck-Medco supports PMPs but is having difficulty managing each state's different requirements – can't we standardize across states? The areas of difference include:

- States collect different data elements.
- Some states require paper reports.
- Serialized Rx # are in some states but not all.
- CA prohibits use of Social Security numbers (SSN) on ID cards or health insurance so MM can't provide the SSNs to PMP states.
- MM can readily provide data monthly, but at least one state requires it every two weeks, making it very difficult to comply.
- Most data elements are limited to 11 digits, but HIPAA will require changes in transmission formats.
- Most states don't have easy methods for correcting data errors.

It would be easier for MM to send every state total information – all data elements any state might wish to collect – and then let each state eliminate the data elements that they do not want. Also, if states use algorithms or check digits, let MM know so they can edit against them.

Mary Ann Wagner, R.Ph., Vice President, Pharmacy Regulatory Affairs, National Association of Chain Drug Stores (NACDS)

The NACDS asks states that are considering a PMP to be aware of issues that affect the community pharmacies, i.e.

- Batch format data transmission is ideal for pharmacies; NACDS opposes real-time data transmission of Rx information to PMPs.
- Pharmacies don't like having to handle duplicate or triplicate prescription forms and sending copies on to states.
- Dispensing physicians should be required to report to PMPs, just as pharmacies.
- The American Society for Automation of Pharmacy (ASAP) standards are good and workable for NACDS pharmacies. NACDS would like ASAP listed in legislation as the data transmission standard.
- Data transmission standards should comply with HIPAA.
- Funding: community pharmacies don't want to be forced to fund PMP programs.
- Confidentiality: NACDS wants only authorized persons to receive Rx information.
- Reporting: NACDS thinks state agencies should be required to make annual public reports regarding operation of their programs.

In addition, NACDS believes that prescribers and dispensers should be exempted from liability or penalties for accessing or failing to access PMP information. In the currently operating PMP states, prescribers and dispensers can access data for their patients in: CA, ID, KY, NV, TN, TX, UT, and WV.

Many states considered PMP legislation in 2002:
New PMP legislation was enacted in TN and VA, and WV reauthorized its program. Legislation is still pending in 3 states: NJ, OH and PA. Legislation went un-passed in six states, and their legislatures out of session for the rest of 2002. An outline of each state's legislation is available in Mary Ann Wagner's slides, see conference book or NASCSA website.

NACDS prefers Boards of Pharmacies as the agency managing state PMP databases. When states require an identification number for patients, it creates a problem for pharmacists, i.e. someone other than the patient picks up 40% of Rx, so obtaining the patient's ID number may be impossible. Also, CA has prohibited use of SSN, and other states are considering similar legislation.

NM repealed their regulations to implement the program, due to opposition from prescribers and pharmacists, particularly around issue of who would fund the program. New legislation may surface next year in NM to address the funding.

Q&A Why is NACDS advocating for ASAP to be listed in legislation (OH didn't include ASAP as transmission standard because no guarantee that ASAP, NCPDP or other standard setting groups will continue in operation indefinitely.)? Response by Mary Ann Wagner: NCPDP is named in HIPAA so it will be around for some time. MM would prefer to have the PMP data elements set as "ASPMP standard." NACDS would accept a list of data elements in the legislation.

Have PMPs had a "chilling effect" on prescribing? Response by Grant Carrow: No, data shows that states with PMP have increasing CS Rx at same rate as states without PMP. Response by Alan Must: Purdue Pharma has seen no chilling effect of PMPs, and is promoting the adoption of electronic monitoring programs. It knows of 13 states considering introduction of PMPs in 2003 and is working with those states' legislatures. Purdue also supports tamper proof prescription pads for all CS. PMPs can also save state funding through reduced investigation time and through better management of Medicaid and identifying people who are misusing Medicaid to obtain CS for diversion (by identifying Medicaid recipients who obtain CS outside of Medicaid).

What is MA doing to stop armed robberies of pharmacies? Response by Grant Carrow: PMPs do not have data that can help stop robberies.

Suggestion from Gene Haislip: Often a "bottom-up approach" is the only viable way to create national programs, i.e. creating a nationwide PMP system can be accomplished state-by-state. This has been the process for many years and there is no reason to change that now. Standardization of data elements and system designs are reasonable changes to make a nationwide system work. The Federal Government might provide funding for standardization, with options that allow states to tailor each program to individual state needs. NASCSA can advocate for this.

Suggestion from David Robinson: A task force of the Alliance, NASCSA, NACDS, manufacturers and others should meet to establish model standards for states and common implementation guidelines and to advocate for adoption by new states.

Illegal Importation of Controlled Substances
Karen Tannert R.Ph., Chief Pharmacist, Bureau of Food and Drug Safety, Texas Department of Health.

Drug imports via mail:
The state of TX has developed a partnership with FDA to inspect imported drug packages at airports and ports. FDA has Customs Mailing Inspection points across the US that are set up to block traffickers using US mail for CI drug shipments. This has expanded with the expansion of Internet drug shipments into the US.

FDA policy permits importation of Rx medicines for personal use, particularly where a medical treatment is not otherwise available in the US. As a practice, most packages with drugs for personal use are allowed through. Unapproved drugs, or drugs intended for commercial resale are stopped.

DEA policy is that the personal medical use exemption does not apply to controlled substances (CS), so CS cannot be imported into US even when intended for personal use by the addressee. FDA is reconsidering its policy vis a vis CS importation, but the review is not completed and no date is set for completion.

US Customs' policy is to inspect packages at the "first port of entry." TX inspects once per week at each point of entry – food staff, and drug staff alternating weeks. Some facilities do and some don't have X-ray capabilities.

In 1999, 9725 separate packages of pharmaceuticals were seized. Staff opened 425 packages at Dallas Fort Worth airport from July 2001 to July 2002: 384 packages were detained -- 90% were in violation of US laws. The United Kingdom is the source of a great deal of illegal drugs, even when another country is listed on the return address. Benzodiazepines top illegal shipments, with opiates the second highest.

Data on seized imports shows a major Tramadol problem on the US West Coast.

Marv Shepherd, Ph.D., Director, Center for Pharmocoeconomic Studies, College of Pharmacy, University of Texas

Mexican Drugs and Problems of Control:
Chartered buses of U.S. senior citizens are going to Mexico to purchase Rx. Individuals go to buy multiple Rx for family members, relatives, and friends. At one El Paso clinic, 80% of the patients go to Mexico to fill their Rx. Up to 25,000 people walk across a bridge to and from Nuevo Laredo in one afternoon. Many of these people carry bags of drugs, much of it CS.

Dr. Shepherd's 1997 research found that 41 million people crossed the Laredo-Mexico border, and that is only one crossing point. US citizens from 37 states were bringing drugs across. The top 15 drugs he

observed being walked into the US had a value of $134 million. An estimated 11,000 Valium dosage units crossed the border each day at that one point – these were the declared drugs – probably only about 10% of quantity actually being brought in. He observed one woman cross the border 4 times in one afternoon. Each time she brought across 50 dosage units of Valium for "personal use."

People go to Mexico because there is easy access, drugs are cheaper, people can buy drugs that are banned in US, and most Rx drugs in the US can be bought without an Rx in Mexico (Rx drugs are sold like candy). 90% of Mexican pharmacies do not have a licensed pharmacist on premises. To sell CS, pharmacies only have to have a licensed pharmacist "on payroll."

To buy CS in a Mexican pharmacy, the patient must have an Rx signed by a Mexican physician. Such Rx are very easy to obtain at prescription mills; the customer tells the doctor what drug he or she wants, the doctor writes out the Rx, and the customer pays $30. Many pharmacies have "runners" who solicit customers to come into shops and buy Rx and drugs.

While many drugs in Mexico have lower prices than in US, they are often counterfeit and some are higher priced, e.g. Viagra and statins. Mexico controls drug prices but pharmacies can sell for less. US Customs will usually allow medications across the border so long as they are not banned in the US. Valium tranquilizers are the drugs most frequently brought into the US: 69.8% of all persons with drugs bring in Valium.

The most significant concern is that counterfeit or low quality products are harming US citizens. Mexico has no quality control on manufacturing of pills/tablets. Even the Mexican manufacturing plants of US based companies are not inspected. It can be very dangerous for a US citizen to take a US produced medication and then switch to Mexican produced version of same product. Also, there are no patient inserts, no instructions for use, labels are in Spanish, and there is no screening for contra-indications or appropriateness of Rx to patient's condition. Dr. Shepherd observed one "pharmaceutical manufacturing plant" that was located in a cave with pill making machines that turned non-pharmaceutical materials into pills.

Most counterfeit drugs in Mexico are from India, Pakistan, and China. Most Mexican pharmacists are not trained in college; they only serve apprenticeships, and they have no continuing education.

In contrast to the unregulated production of medications for patient consumption, the FDA approves most Mexican produced pharmaceutical raw materials (Mexico produces 65% of world's raw materials for pharmaceuticals).

During the 1990s, Rohypnol was the major drug brought in from Mexico (a date rape drug). Now OxyContin is crossing the border into US. The most frequently counterfeited items are drugs, tobacco, clothing (logos on brand name clothing), and cosmetics.

Recommendations: The US should block importation of CS from Mexico. This will not hurt senior citizens as few use CS, and the risk of injury is huge. The federal government and states should conduct public education to warn people of dangers of buying products with no quality control, and run public service announcements in media in communities all along US-Mexico border.

FRIDAY, OCTOBER 25, 2002

SAMSHA Update
Nick Reuter, R.Ph., Deputy Director, Office of Pharmacology & Alternative Health, Substance Abuse and Mental Health Services Administration (SAMHSA)

Addiction Treatment Developments:

Methadone/ORLAAM Final Treatment Regulation has been issued. NASCSA's resolutions in 1998 and 2000 resulted in modifications to the final rules and greater involvement of state controlled substances authorities and boards of pharmacy in implementation of the regulations.

Opioid Treatment Programs (OTP):
There are about 1,200 OTPs in the US. They are in all states except six, MS, NB, SD, MN, WY and ID. The greatest numbers of OTP patients are in the Northeastern US and CA.

The OTP final rule became effective in May 2001. It shifted oversight of OTP from FDA to SAMSHA. The regulatory control is based in accreditation, which is the responsibility of JCAHO, State of Washington, and other independent accreditation groups.

"Take home" rules allow a patient in OTP for a period of 0-90 days to have 1 take home dose per week. The "take homes" increase the longer a patient is in treatment, rising to 30 days' after 2 years of treatment (specifics are in N. Reuter's power point slides at NASCSA's website).

Office Based Opioid Treatment (OBOT):
Trials for OBOT have been underway for years, with about 700 patients currently involved. The number probably will increase substantially as OBOT becomes widely available.

OBOT can move forward now because new federal regulations have been finalized allowing buprenorphine use in OBOT. SAMSHA has set up its oversight structure and is ready to move forward and SAMSHA has approved four accreditation bodies, including one state, WA.

How many states must change regulations to allow OBOT? States that need to change regulations are asked to let Nick know.

The authorizing statute for OBOT is the Drug Addiction Treatment Act, which became law as part of the Children's Health Act of 2000. The federal regulations set a maximum of 30 patients per physician; medications are limited to only CIII, CIV, and CV narcotics specifically approved for maintenance or detoxification (buprenorphine is the only one approved so far).

To practice OBOT, physicians must have a subspecialty designation from American Society of Addiction Medicine (ASAM), American Board of Medical Specialties, or American Osteopathic Association (AOA). They must have participated in trials or have special training from ASAM, American Academy of Addiction Psychiatry, AMA, AOA, American Psychiatric Assoc., or an organization designated by DHHS. Physicians must submit waiver notification forms (electronically or by fax). DHHS must decide within 45 days; if DHHS approves or makes no determination, DEA must issue a special registration for OBOT, i.e. an "X" as the first character in DEA Registration number.

Federal Pre-emption:
A state cannot block a practitioner from dispensing or prescribing narcotics for maintenance or detoxification unless the state enacts a special law prohibiting it. The process for a state to follow if they chose to block practitioners is briefly outlined in N. Reuter's slides at the NASCSA Website.

Physicians approved for OBOT:
So far, 750 physicians have submitted waiver notifications and 240 have been approved by DHHS. Notifications have been received from all states except SD, ND and AK. The notifications are in proportion to the number of Methadone treatment programs in each state:

- NY – 120
- CA – 85
- PA – 45
- NJ – 35
- TX – 30

The average years out of medical school for the physicians who have submitted notifications are 23.5 yrs. Their specialties are: 31% in psychiatry, 28% in addiction medicine, and substantial numbers in internal

medicine and family medicine. Nearly half of the physicians, 41%, indicate they have treated opioid dependence with methadone. Only 5% have no experience treating opioid dependence. Fully 80% have treated opioid dependent patients for 3 or more years. Most of the physicians have agreed to being listed on SAMHSA's Treatment Facility Locator.

SAMSHA is hoping to issue waivers to cover areas where no OTP is available, but that has only happened in a few places. Some are in un-served areas of NY and VA.

An expert panel is developing Clinical Practice Guidelines for Buprenorphine.
SAMSHA is also working with State Medical Boards to develop a guidance document to help medical boards review to assure OBOT is according to approved medical standards. This will be similar to medical board guidelines for pain treatment.

Emerging Issues:
Group practices want to handle more than 30 patients; the current limit is 30 patients per group. So even large groups with many physicians can only treat 30. Buprenorphine cannot be used by OTP (only methadone and ORLAAM are approved for OTP). However, physicians who work with OTP can individually treat up to 30 patients each, so there is discussion about allowing OTPs to use buprenorphine.

State pre-emption expires in 3 years after approval of buprenorphine as drug of treatment. Thus, state pre-emption will expire in October 2005. For a state to impose restrictions in the mean time, it has to follow protocols. Any state considering this can discuss it directly with N. Reuter.

Confidentiality / Data to states' Prescription Monitoring Programs (PMPs):
Physicians are considered to be OTP "programs" subject to 42 CFR Part 2. Thus, patients must consent to disclosure, including physician disclosure to pharmacies. This will allow pharmacies to submit Rx data to states' PMPs.

Off label use of buprenorphine is not prohibited. But manufacturers are not promoting it for analgesia because the addiction treatment dose is higher than for analgesia. Will this become a potential diversion problem? Pharmacists should check each patient to verify if they have the special ID. If not, pharmacists should verify the Rx with the prescriber to assure it is valid.

Subutex, and Suboxone (with nalaxone).
FDA approval requires post-marketing surveillance and a risk management program. Surveillance is important because there have been increases in drug overdose deaths recently, particularly in Maine, Virginia, North Carolina, and Florida. Methadone related deaths have increased too, and Methadone use for analgesia is increasing. CSAT is launching an initiative to collect better information on these deaths.

How states can check which physicians have approved waivers:
www.findtreatment.samsha.gov
1-866-287-2728
info@buprenorphine.samsha.gov

New Strategies and Products for the Analgesic Market
Terese Ghio, Senior Director, Government Affairs and EH&S
Ligand Pharmaceuticals, San Diego, CA

Ligand is a biotech company, focused on basic research rather than a pharmaceutical manufacturer. It is a small company that farms out production to pharmaceutical manufacturers via contract. The company is based in San Diego, CA, and has 400 employees. They currently market four "orphan" cancer treatment products and AVINZA, 14 products are in Clinical/IND track, and 8 are in pre-clinical trials. The company is working toward profitability. Its core technology is based upon selective gene regulation (nuclear receptors) intercellular receptor technology from Salk Institute in 1989.

Thomas Compton, Senior Director, Marketing – Supportive Care.

AVINZA, is a new CII product that is morphine sulfate extended-release capsules. It was launched on July 1, 2002. Elan manufactures the product for Ligand.

Sales of sustained release analgesics increased from $480 million in 1997 to 2.3 billion 2001. From the first half of 2001 to the first half of 2002, the sales had increased by 17% from $1.1 to $1.3 million. This was primarily OxyContin, 60%, and Duragesic, 33%. OxyContin sales grew from $130 million in 1997 to $1.467 billion in 2001. Using IMS data, OxyContin dollar sales growth slowed to 9% in first half of 2002, while Duragesic grew by 45%. The sustained release morphine products decreased in sales by 11% from the first half of 2001 to the first half of 2002.

The number of prescriptions for sustained release analgesics increased from 2.6 million Rx in 1997 to 11.8 million in 2001. From the first half of 2001 to the first half of 2002, Rx increased from 5.9 million to 6.1 million. This increase was entirely due to Duragesic Rx, which increased by 0.5 million Rx while OxyContin Rx decreased by 0.2 million.

Internal medicine, family practice and anesthesiology are the specialties of the primary prescribers of sustained release analgesics, accounting for more than 50% of the total Rx.

Avinza contains sustained release beads (90%) and immediate release beads (10%). Avinza can be given once daily for treatment of moderate to severe pain. It is used to reduce pain intensity and stiffness equivalent to MS Contin (MS Contin has to be taken every 8-12 hours), but sleep is better with Avinza. It approaches maximum morphine concentration more quickly and maintains it more evenly over 24 hours. Avinza can be taken at any time; it is not meal related. It can be swallowed as a whole pill or with contents sprinkled on applesauce. There is a risk of rapid release if Avinza is chewed, crushed, or dissolved, with possibility of overdose or fatality.

Avinza's adverse effects are similar to other opioids. It is contraindicated for respiratory depression or adverse reaction to morphine. Avinza is available for opioid-tolerant patients in 60 mg, 90 mg, and 120 mg capsules. There are warnings about cautious release if patients have one of several diseases or conditions – see slides at www.nascsa.org

Carol Manifold, Pharm.D., FASHP, Vice President, Professional Services, Ligand

Risk Management Plan for Avinza:
FDA requested such a plan for approval of the product. Ligand plans a major effort to identify any adverse effects from Avinza, including a voluntary adverse event reporting system and literature review. Safety information is provided to patients in package inserts. Pharmacists are advised what to look for vis a vis package tampering, drug seeking patients, etc. Ligand is sending letters to DEA, State Pharmacy Boards, Poison Control Centers, and major medical associations. The company requires mandatory training for field representatives and they must pass tests of knowledge.

An observational, post marketing study has been designed and the protocol is at the FDA for approval. They plan to monitor and track DAWN, to operate an adverse reporting system, conduct literature reviews, check Internet chat rooms and keep up with media articles.

Ligand is so committed to avoiding diversion and adverse outcomes that it put risk management at the vice presidential level and integrated it through many departments. Regular group meetings are held.

Ligand is setting up a risk assessment panel to review use and risks. The company intends to include law enforcement and will ask DEA for advice. They have found that people like the new product and appreciate safety activities.

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Thomas V. Compton
Senior Director, Marketing – Supportive Care
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Q&A: Is there a medical basis for prescribing more than once daily? Response by Thomas Compton: No!

Q. Has the company found ways to limit abuse? Otherwise, they should expect that it will be crushed and injected, and be trafficked for addiction. Response by Carol Manifold: They will watch through monitoring and hope to avoid this through risk reduction practices.

NASCSA Final Business Session
Review of quorum – The quorum for the conference was established with 21 or more states present at beginning of general session, in accordance with the By-Laws.

Audit Committee
Jim Giglio, Chair, reported all finances are in order.
Report adopted by unanimous vote.

Resolutions Committee
Grant Carrow, representing the committee, reported:
(the full text of adopted resolutions is available at www.nascsa.org)

Resolution 2002-01:

NASCSA opposes passage of S. 3303 and H.R. 5503, the National All Schedules Prescription Electronic Reporting Act of 2002" and recommends that Congress instead provide additional funding for the Harold Rogers Prescription Monitoring Program to support states in the development of programs ....

The resolution was amended:
"Whereas" paragraph two is deleted; "Whereas" paragraph 4 is amended by moving "NASCSA" in front of "Alliance" and the full names of both organizations are spelled out in front of their abbreviations; and
"Therefore" paragraph 1 is amended by changing S. 3303 to S. 3033.

Motion to adopt with amendments made by Grant Carrow, seconded by Charles Ray Nix and passed by unanimous vote.

Resolution 2002-02:

The "Therefore" paragraph is amended to read:
"Therefore, be it resolved that the National Association of State Controlled Substances Authorities (NASCSA) adopts the "Prescription Monitoring Program Model Act" of 2002 as a joint document with the Alliance of States with Prescription Monitoring Programs and encourages states to adopt its principles."

Motion to adopt as amended made by Grant Carrow, seconded by Tim Benedict, and passed by unanimous vote.

Motion to reconsider and rescind Resolution 2002-01, made by Grant Carrow, seconded by Jim Giglio and passed unanimously.

Resolution 2002-03:

New resolution introduced, which is the same as Resolution 2002-01, but a new "Whereas" paragraph 2 is added to read: "Whereas the National Association of State Controlled Substances Authorities (NASCSA) and the Alliance of States with Prescription Monitoring Programs (Alliance) have developed and adopted the Model Prescription Accountability Act of 2002 that incorporate the current best practices of existing programs."

Motion to adopt made by Grant Carrow, seconded by Charles Ray Nix, and passed by unanimous voice vote.

Nominating Committee
Tim Benedict, Chair

Slate of proposed officers and Executive Committee members:
President: Bill Ward
Vice President: Dana Droz
Secretary Treasurer: Jim Giglio
Executive Committee – 2-year terms:
Keith MacDonald
Charles Ray Nix

The nominated slate of officers was elected unanimously.

David Dryden and Karen Tannert will continue as Executive Committee members for an additional year.

Pain Management in the 21st Century – A Regulatory Perspective
Bruce Canaday, Pharm.D., Director, Department of Pharmacotherapy, Coastal Area Health Education Center, and Clinical Professor, Pharmacy and Medicine, University of North Carolina.

Health care professionals and governmental agencies agree that Rx pain medications have tremendous therapeutic value and they can be deadly when used incorrectly. Also, while Rx drug abuse is not new, it is increasingly common.

The media has few if any constraints on what they say and, in fact, can say almost anything as long as their targets cannot prove intent to harm. Maine newspaper said that OxyContin is a gateway drug for heroin abuse, when data indicates it is the opposite.

Of those who reported abusing OxyContin, 98% had a history of abusing other drugs: 67% reported ever using cocaine or heroin, and 21% reported using heroin. Nearly 90% of non-medical OxyContin users reported ever using two or more other substances non-medically. The National Household Survey on Drug Abuse reported 1.6 million Americans used pain relievers non-medically for the first time in 1998, an increase from 500,000 first time users per year in the 1980s. The increases in new users from 1990 to 1998 were: pain relievers 181%, tranquilizers 132%, sedatives 90%, and stimulants 165%.

In 1999, an estimated 4 million people, 2% of population aged 12 and older, were using Rx drugs non-medically within the last month; 2.6 million were Rx pain relievers users, 1.3 million were tranquilizer and sedative users, and 0.9 were stimulant users.

Is there a prescription drug abuse problem? Yes, and it is getting worse. Are pain medications out in front? Yes, by 25% and getting worse. Is OxyContin a drug of abuse de jour? Yes.

Things pharmaceutical manufacturers can do to reduce abuse:
Several companies are trying to design CS delivery mechanisms that prevent abuse. For example they are trying to reformulate products with opiate antagonists (naloxone or naltrexone) so if the drug goes directly into blood stream, the antagonist will block the effect, like Talwin NX. They can also try to alter the release system to prevent rapid release or block extraction of the opiate.

In addition, manufacturers should conduct educational programs for health professionals– led by experts in pain management – regarding proper use of CS and how to guard against misuse and abuse. The manufacturers should distribute practice guidelines, e.g. Federation of Medical Boards' guidelines on pain management, and educate the public, teachers, parents and children. Manufacturers should work with the Community Anti-Drug Coalitions of America (www.cadca.org) and other organizations, and work with national groups like NASCS, NAG, NADDI. Also, manufacturers should encourage use of tamper-resistant prescription pads, and battle cross border smuggling by changing identifying markings on legitimate products exported to Mexico and Canada to identify to which country it is being shipped. In addition, manufacturers should fund research on the prevalence and nature of controlled substances abuse and diversion.

Physicians must treat patients as patients, and if they do so, drug seekers will occasionally fool them. But physicians can use the CAGE questionnaire as part of history, get full drug history of Rx and OTC drugs being taken and do good physical exams (look for injection sites). Put in writing what a patient can expect from the physician and what the physician can expect from the patient. Physicians should watch for sudden increase in amount of medication needed, or frequent requests for refills, and then evaluate if the cause is tolerance or abuse. Physicians should assess functional status, e.g. sleep patterns, etc., and can observe patients' behavior by use guidelines like Portnoy's criteria, i.e. patients forging or stealing Rx, selling Rx medications, repeatedly escalating dosages, or obtaining drugs from multiple sources.

Pharmacists should build solid relationships with patients in pain. This will help identify diversion and allow the pharmacist to refer people to chemical dependence, detoxification and treatment. They should think twice about Rx for unusually large quantities of narcotics and ask questions of patients. Pharmacists should watch for altered or forged Rx, and use "hotlines" (e.g. a fax alert system) to warn state and other pharmacies when diversion is identified. They should also check with the prescriber when they question an Rx.

Law enforcement roles:
Prescription Monitoring Programs are useful, though triplicate prescriptions are not; the NY State Public Health Council reported that 71% of physicians used less effective drugs to avoid prescribing on a triplicate prescription form. Regulators should be careful not to over regulate or take actions that will reduce patient access to drugs they need.

Rx medications can improve and save lives, but they can be deadly when used improperly. As Thomas Aquinas said "Nothing is intrinsically good or evil, it is the manner of usage that makes it so."

Q&A: Why does the slide about PMPs criticize triplicate prescriptions by referencing a study mentioned in a NY State Public Health Council report, but does not mention the deficiencies in that study and the Council's conclusion that serialized prescriptions forms are of such value that they should be continued in a new, single copy format? Response by Bruce Canaday: I wasn't aware of these questions and will go back and reexamine the NY State Public Health Council report.

The National Forensic Laboratory Information System: Providing a Perspective on the US Drug Problem from a Nationwide Sample of State and Local Forensic Laboratories
Frank Sapienza, Chief, Chemical & Evaluation Section,
Office of Diversion Control, US Drug Enforcement Administration.

National Forensic Laboratory Information System (NFLIS):
DEA contracted with Research Triangle Institute (RTI) to set up the system. A feasibility study was conducted in 1985 and was implemented in 1997. The system collects drug analysis results from state and local crime laboratories: 177 out of 300 labs have joined; 154 are reporting regularly. The system is growing toward all labs reporting.

NFLIS provides accurate, chemically verified data in support of drug scheduling, in addition to data from DAWN. It allows tracking of trends in drug abuse regionally and nationally, and an early warning system for new drugs of abuse. The system is compatible with DEA's seven labs.

The initial labs were selected to enable national and regional estimates; the system is voluntary with modest assistance provided to the labs. The data elements collected are available in power point slides at www.nascsa.org. The system produces reports annually and quarterly. The data can be accessed by direct dial with browser access. This provides access to case-level data to the submitting lab, to DEA, and to RTI only. Summary data are available for others.

NFLIS provides scientifically verified information on a large number of analyses. It provides legally defensible information with national and regional coverage, and it facilitates information exchange and collaboration.

Valley Rachal, Senior Program Director, Research Triangle Institute (RTI)

RTI is a not-for-profit research unit associated with the University of North Carolina, and Duke University. Taxol was developed by RTI and they gave the patent to Bristol Meyers.

National Estimates:
Annual drug caseload reported to NFLIS varies widely by state. Some only have 5,000 cases per year up to 100,000-200,000 in CA & NY. Estimates are based on reports from a sample of 29 state and 31 local labs that are representative of the nation and each region.

Sample data are weighted to make national estimates. Of the drugs analyzed, 89% are the top four: #1cannabis, #2 cocaine, #3 methamphetamine and #4 heroin. Alprazolam is the most frequently reported Rx controlled substance, followed by hydrocodone, oxycodone and diazepam. The data show regional differences: in the Northeast, cannabis is #1, followed closely by cocaine; in the Midwest, cannabis is #1; in the South, cocaine is #1; in the West, methamphetamine is #1.

Analysts compared NFLIS data to DAWN Emergency Department mentions. They found that the licit controlled substances, benzodiazepines and narcotic analgesics account for only 4% of the NFLIS cases, but account for 18% of the DAWN overdose mentions.

Narcotic Analgesics:
Hydrocodone represented 37% and oxycodone represented 32% of the 16,000 narcotic analgesic cases reported by the NFLIS system nationally in 2001. In the Northeast, oxycodone cases exceeded all the other narcotic analgesics combined; in the Midwest, oxycodone was only slightly ahead of hydrocodone; in the South, hydrocodone led oxycodone by a small margin; and in the West, hydrocodone cases were more than twice the number of oxycodone cases.

Benzodiazepines:
Alprazolam cases were more than half of the almost 15,000 benzodiazepine cases nationally in 2001. Diazepam was 2nd and clonazepam was 3rd. These three drugs accounted for more than 90% of all benzodiazepines. In the Northeast, alprazolam exceeded the other benzos by a large margin, with clonazepam second; in the Midwest and South, alprazolam led by a wide margin, but diazepam was second; in the West, diazepam led all others, with clonazepam second and alprazolam a distant third.

Club drugs:
MDMA (called Ecstasy) represented 82% of the 12,000 "club drug" cases nationally in 2001. Ketamine was second with 10%. MDA and GHB were in third and fourth places, respectively, and, combined with the first two, accounted for more than 99% of the club drugs. Regionally, the proportions were about the same as at the national level.

Stimulants:
Methamphetamine was the leader, accounting for 92% of the 106,000 stimulant cases nationally in 2001. Pseudoephedrine, amphetamine, ephedrine and methylphenidate rounded out the top 5 stimulants, and combined with Methamphetamine, were 99% of all stimulant cases. The Northeast did not follow the national pattern because "Other stimulants," including methylphenidate, exceeded methamphetamine by a 2:1 ratio. In the rest of the country methamphetamine exceeded all other stimulants combined, by a very high degree.

Steroids:
There were only 1,200 steroid cases reported nationally in 2001, with testosterone leading with 46% of all cases.

Combination drugs:
Of the 12,000 combination drug cases, 90% were combinations of illicit drugs. Among the combination cases involving prescription drugs, hydrocodone with acetaminophen had the largest number of cases, with 557.

The NFLIS has found that the purities of heroin and cocaine vary widely between cities in the US. They also found that 72% of all cases in South Florida were cocaine, which is different than the nation as a whole, where cannabis leads.

For the future, the DEA and RTI plan to continue recruiting state and local labs and to begin recruiting the Federal labs. They also plan to expand the national estimating capabilities and to conduct special studies.

Note: detailed information from this presentation is available on the power point slides at www.nascsa.org

SATURDAY, OCTOBER 26, 2002

The Implications of HIPAA: What Is It and Why Should You Care
Brian Gallagher, R.Ph., JD, General Counsel and HIPAA Compliance Specialist, TechRx

Health Insurance Portability and Accountability Act of 1996 (HIPAA):
The bill was enacted to make insurance transferable as people move or change jobs. As a result, its provisions were designed to make transfers possible, including standardization of data elements, forms and procedures. The bill also had to provide protection for patients' privacy. Privacy regulations have been developed in federal regulations 45 CFR 160 & 164. These address several areas, as follows:

Transaction Sets were defined and became effective October 16, 2002. These include NCPDP 5.1 (National Council of Pharmacy Data Processing) 5.1 as the new standard for transmission of all prescription information. The rules also propose to simplify administrative procedures and expedite data transfer. The Administrative Simplification Compliance Act of 2002 allows delay from October 2002 to October 2003 for the shift to NCPDP 5.1. This creates a problem because payers can either continue using NCPDP 3.2 (existing standard) or adopt NCPDP 5.1. It will be very difficult for pharmacies since they must be able to send data both ways.

This delay, however, does not affect the Privacy Act, which goes into effect on April 14, 2003.

The Security Rules for HIPAA are not yet final. They will provide for physical security such as locking up computers at night. They will also require administrative and technical security procedures. The security

rules will provide some flexibility based upon reasonableness. For example, they will address "scalability," a pharmacy's size and amount of funds will dictate the level of security the pharmacy must implement. Negligence will be determined by experts, initially, but ultimately will be decided by court suits; the Products Liability Law will be brought to bear in court suits. The "reasonableness" standard will evolve over time and through court cases, i.e. through "retrospective scope."

The Privacy Rule has just been finalized. Differences between privacy and security rules will be settled in favor of the privacy rules. Covered entities must use good faith efforts to give notice and receive written acknowledgement before using the minimum necessary amount of protected health information for patient treatment, payment, or health care operations. The Privacy Rule allows transfer of information for treatment, but this applies to a particular patient, not to a general population. The Rule allows for transfer of information for payment, i.e. the information necessary to obtain third party payment can be transferred. Likewise, information for Health Care Operations can be transferred, but only the minimum amount necessary. This will affect programs that contact patients about treatment alternatives, disease state monitoring, and the sale of businesses.

For other uses, people seeking patient information must obtain a signed authorization from each patient. Patients have the right to access their own records, and to receive an accounting of disclosures of their records to other parties. Thus, pharmacists are required to maintain records of who accesses the records.

Personally Identifiable Health Information is described in and regulated by section 164.501. Covered Entities are described in and regulated by section 160.103, which covers both insurance companies and pharmacies.

Written Acknowledgement of Notice (section 164.506) is mandatory:
Beginning April 2003 pharmacists and physicians must explain privacy rights to patients and patients must acknowledge in writing that notice was given. This must be done once for each patient (once for an entire pharmacy chain) on the first date of service. Notice and acknowledgement can be done electronically, by mail, or in person. Even mail order pharmacies must comply. Providers must use "best efforts" to get written acknowledgements and must document such efforts. If that is done and the patient does not provide the written acknowledgement, the provider is not in violation of the regulations.

Pharmacists can ask patients to sign the acknowledgement as part of signing the receipt book for picking up an Rx, so long as it is clear that the patients are acknowledging that their privacy rights were explained, and the signatures are not for another purpose, such as a waiver of pharmacist counseling. With electronic notices, the system should capture the individual's acknowledgment of receipt electronically.

Patient consents are optional under HIPAA, and will not be required.

Notice (Section 164.520 of the regulations):
A Notice of the confidentiality requirements must be easily available for all patients. It is a complicated document, and must be posted in each pharmacy. The notice must list patients' rights, contact information, and how to file complaints. The regulations require a header with specific language; descriptions of patient record uses without consent, including examples of treatment, payment, and health care operations exemptions; where data may be used; information about refill reminders; and other information. The notice must also state that the provider will comply with the more stringent law, federal vs. state. Detailed requirements in federal and state laws, patients' rights and pharmacists legal duties must also be included.

Authorizations (Section 164.508 of the regulations):
Authorizations must be obtained from patients if an activity doesn't fit into treatment, payment, or health care operations exemptions. Authorizations are required for things like marketing programs by pharmaceutical manufacturers. Such authorizations are not the same as consents or acknowledgements. Such access cannot be granted through the acknowledgement process. Authorizations must be complete and inform patients how they can opt out if they do not want to participate.

Audit trails:
Read only issue:under the security rule, if someone sees information regarding any patient, there must be a record of that "reading." A literal reading of this section would indicate that if a John Smith comes in for a Rx fill and the pharmacist has to go through 10 John Smith's records to find the correct record, the pharmacist must record the "read" in every record. Also, if a pharmacist calls the doctor's office or discusses a patient's record with a pharmacy technician, that has to be recorded. However, if the "read" is the minimum necessary for treatment, payment, or health care operations, the pharmacist doesn't have to record it. Any other observation of records must be recorded and made accessible to the patients.

Law enforcement:
Disclosure to a patient that a law enforcement agency has examined the patient's record is not required. Other exemptions from disclosure are permitted. This includes denial of access to protect victims of abuse or domestic violence. Disclosure is also not required for record reviews required by law, public health activities, health oversight activities (this exemption may not apply to investigation of a particular individual), or judicial and administrative proceedings (but the patient must be notified so the patient can object or seek a restraining order).

Crime on the premises:
Pursuant to due process, a health care provider can disclose information in an emergency, but the disclosed information must be limited to the amount necessary for identification and location of a suspect, e.g. name, address, and date of birth. In such cases, authorities may request that the release of this information not be disclosed to the patient or noted in the patient's record. There is a 30-day limit on this unless law enforcement presents a written request for more time and states that disclosing the information to the individual would be "reasonably likely to impede the agency's investigation" and specifies the time limit for suspension of recording within patient's record. The covered entity (pharmacy) must document oral requests including the name of the agency and official's name.

Whistleblowers can disclose information to regulatory people and to lawyers.

De-identification: If 19 identifiers are removed from patient records, the records are considered de-identified and can be disclosed. As an alternative, a health care provider can have a statistician certify that sufficient data items have been removed to prevent identification of individuals.

Business associate contracts must apply the same constraints on contractors as upon the contracting entity.

Providers are allowed to deny a patient access to his/her record if access would harm someone. Patients have the right to request changes in records to correct inaccuracies. A provider can deny the request if the provider did not create the record or if the record is "reasonably accurate and complete;" the provider must put the reason for the denial in writing. A patient can appeal a denial, the provider can respond, and all the documentation must be kept in the patient's record.

Providers must sanction employees and business associates who violate provisions.

The penalties for violating HIPAA increase for more serious violations, up to 10 years imprisonment and $250,000 fines if violations are for "commercial advantage, personal gain or malicious harm."

Q&A: Are state prescription monitoring programs (PMPs) "covered entities" that must give notice to patients or to keep accounting of disclosures of information to other entities? Response by Brian Gallagher: PMPs probably are not "covered entities," and, therefore, do not have to comply with the requirements. The larger question is what record, if any, should the pharmacies keep of sending the information to the state PMP – someone will need to research that question.

Regulation of Precursor Chemicals and Its Impact on Legitimate Use
Patricia Cruse, Chairperson, GBL/BDO Panel, American Chemistry Council
Manager, Product Stewardship, BASF, North Carolina

Gamma Butyrolactone (GBL) and 1,4-Butanediol (BDO):
The American Chemistry Council CHEMSTAR panel was chartered in 2000.
Membership includes Crompton, BASF Corp, BP, ISP, and Lyondell.

GBL/BDO Panel Goals:
The panel's goals are to prevent diversion, promote awareness of and compliance with regulations, partner with state and federal regulators, and communicate issues to customers/stakeholders.

GBL:
US consumption of GBL is about 350,000 metric tons per year. It reacts to produce other chemicals. By itself or in combination with other chemicals it makes excellent solvents for electronic parts and agricultural chemical manufacturing.

BDO:
US consumption is about 300,000 metric tons per year. It is used to make Spandex; hard and soft plastics; polyurethane systems like skateboard wheels, golf balls, and car bumpers; and solvents for coatings and ink.

As Illicit drugs:
GBL and BDO are used for date rapes They are both metabolized in humans to produce gamma hydroxybutyrate (GHB), the "date rape drug."

The GBL/BDO panel has worked with DEA and six states' AG and legislators to devise means to prevent diversion. The panel has common goals with NASCSA, the most important of which is to prevent diversion. They insist that chemical manufacturers know their customers, set up security at their plants and storage facilities, and conduct employee training and customer training.

Internet sales of GBL or BDO through Canada are a diversion problem. Products are sold as "flavored ink jet cleaner," or "finger nail polish cleaner -- great for finger nail parties."

When a State schedules BDO or GBL in Schedule II-V, GBL/BDO panel members determine the need to register and obtain permits, determine other state requirements and then inform customers and distributors so they can comply.

If a state were to put GBL or BDO into Schedule I, it would block chemical companies from shipping the chemicals into that state and, thus would block manufacturing of products that require GBL or BDO. That could force manufacturers to move to other states where GBL and BDO are permitted.

Partnerships with NASCSA:
The American Chemistry Council (ACC) wants to work with states through NASCSA and asks NASCSA to help them keep aware of pending statutes/regulations. ACC wants to help NASCSA understand the uses and end products for GBL and BDO and how their chemicals are shipped, stored and used – safely and with adequate security.

Closing Remarks
Bill Ward, President of NASCSA

Thank you to all who helped to plan and run the conference!